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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/620,155

07/14/2003

Douglas T. Gjerde

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PHYNEXUS, INC.

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EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/620,155	Applicant(s) GJERDE ET AL.	
	Examiner LORE RAMILLANO	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/15/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/4/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Status of Claims

2. In applicant's reply filed on 2/15/08, applicant cancelled claims 25-34. Claims 1-22 are pending and are under examination.

Prior art rejections

3. The rejections over the prior art are withdrawn. New rejections follow.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined

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under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. **Claim 1** is rejected under 35 U.S.C. 102(e) as being anticipated by Tuvim (US 6527951).

Tuvim discloses a chromatographic column comprising: a column body (25) having an open end, an open lower end, and an open channel (i.e. 29) between the upper and lower end of the column body; a bottom frit (11) bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit (11, col. 4, lines 2-3, the other end of 29) bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, the top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber (i.e. col. 3, line 63 to col. 4, line 1); and a bed of extraction (i.e. col. 3, line 63 to col. 4, line 1) media positioned inside the extraction media chamber.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1-3, 9, 10, 14, 15, and 19-22** are rejected under 35 U.S.C. 102(b) as being anticipated by Colpan (US 5652141) in view of Tuvim.

Colpan discloses an extraction column comprising: a column body (40) having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit (23) bonded to and extending across the open channel, the bottom frit having a low pore volume; a

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top frit (23) bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, the top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber (between 23 and 23); and a bed of extraction (20) media positioned inside the extraction media chamber (i.e. column 3, lines 14-44).

Colpan further discloses that the bottom frit is located at the open lower end of the column body; the bottom frit is a membrane screen and the top frit is a membrane screen, which comprises a polymeric material; the column body comprises polypropylene; membrane screen made of nylon or polyester; a column body attached to a peristaltic pump; and a lower tubular member comprising the lower end of the column body, a first engaging end, and a lower open channel between the lower end of the column body and the first engaging end; and an upper tubular member comprising the upper end of the column body, a second engaging end, and an upper open channel between the upper end of the column body and the second engaging end, the top membrane screen of the extraction column bonded to and extending across the upper open channel at the second engaging end, wherein the first engaging end engages the second engaging end to form a sealing engagement (i.e. column 3, line 14 to column 4, line 33).

Colpan does not specifically disclose having a top frit and bottom frit that are less than 350 microns thick.

Tuvim discloses a chromatography column with filters having minimal volume. A stamped screen disk is coated with fluorocarbon polymer on both

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sides, leaving a center area open. The fluorocarbon polymer coating serves as a gasket, providing reliable sealing for pressure up to approximately 10000 psi.

The chromatography column comprises a fitting having an internal cavity. A fluorocarbon polymer coated screen is placed within the cavity. A threaded capillary tubing is screwed inside the cavity. At the end of the capillary lies a compression screw solvent tubing connection. (i.e. Abstract).

It would have been obvious to a person of ordinary skill in the art to modify Colpan by having a top frit and bottom frit that are less than 350 microns thick because Tuvim discloses that it is widely known in the art that the smallest thickness of all available filters is 0.75 micron. Tuvim further discloses it would be advantageous to have a thinner filter because its volume would be smaller. (i.e. col. 1, lines 38-44).

8. **Claim 1** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brewer (US 6566145) in view of Tuvim.

In figure 2, Brewer discloses an extraction column comprising: a column body (10) having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit (24) bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit (22) bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, and top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber (between 22 and 24); and a bed of extraction (18) media positioned inside the extraction media chamber (i.e. column 3, lines 3-36).

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Brewer does not specifically disclose a frit less than 350 microns thick.

The disclosure of Tuvim is indicated above. It would have been obvious to a person of ordinary skill in the art to modify Brewer's frits to have a frit less than 350 microns thick because Tuvim discloses that it is widely known in the art that the smallest thickness of all available filters is 0.75 micron. Tuvim further discloses it would be advantageous to have a thinner filter because its volume would be smaller. (i.e. col. 1, lines 38-44).

9. **Claims 1-6, 9-12, 14-15, and 18-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro ("Hargro," US 6139733) in view of Tuvim.

In figure 2, Hargro discloses an extraction column comprising: a column body (22) having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit (26) bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit (22) bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, and top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber (between 22 and 26); and a bed of extraction (28) media positioned inside the extraction media chamber (i.e. column 2, lines 30-42).

Hargro further discloses that the bottom frit is located at the open lower end of the column body (Fig. 2); the extraction media comprises a packed bed of gel-type packing material (i.e. column 2, lines 37-42); the extraction media comprises an affinity binding group (i.e. column 2, lines 37-42); the column body comprises polyethylene (i.e. column 4, lines 15-20); a syringe (fig. 6); an upper

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end of the column body is attached to a pump (14, fig. 1); and a lower tubular member comprising the lower end of the column body, a first engaging end, and a lower open channel between the lower end of the column body and the first engaging end; and an upper tubular member comprising the upper end of the column body, a second engaging end, and an upper open channel between the upper end of the column body and the second engaging end, the top membrane screen of the extraction column bonded to and extending across the upper open channel at the second engaging end, wherein the first engaging end engages the second engaging end to form a sealing engagement (i.e. Fig. 1, 2, 5, and 6; column 2, lines 30-41).

Hargro does not specifically disclose a frit less than 350 or 200 microns thick; a frit having a pore volume equal to 10% or less; a frit having a pore volume of 1 microliter or less; and a membrane screen made of nylon.

The disclosure of Tuvim is indicated above. It would have been obvious to a person of ordinary skill in the art to modify Hargro's frits to have a frit less than 350 microns thick because Tuvim discloses that it is widely known in the art that the smallest thickness of all available filters is 0.75 micron. Tuvim further discloses it would be advantageous to have a thinner filter because its volume would be smaller. (i.e. col. 1, lines 38-44).

10. **Claims 7 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro in view of Tuvim, as applied to claims 1-6, 9-12, 14-15, and 18-22 above, and further in view of Smith et al. ("Smith," US Pub. No. 2004/0253687).

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The disclosure of Hargro is discussed above. Modified Hargro does not specifically disclose utilizing agarose and sepharose and an affinity binding group, such as Protein A.

Smith discloses an apparatus for extracting proteins of interest comprising an "affinity tag," which is a molecule, ligand or polypeptide attached to a protein (polypeptide) of interest. Examples of affinity tags include, but are not limited to, hexa-histidine, other metal tags, Protein A, and other protein or small molecule tags which may assist in the isolation and purification of expressed proteins.

Furthermore, Smith discloses an "affinity matrix," which include chromatography medium, such as agarose, cellulose, Sepharose, Sephadex and other chromatography medium, polystyrene beads, magnetic beads, filters, membranes and other solid-state materials bound to ligands or substrates which bind to the affinity tag of choice. (i.e. [0052]-[0053], [0084]). It would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically utilizing sepharose or agarose since the modified Hargro discloses utilizing chromatography medium, which is a term commonly known in the art that pertains to gel-based chromatography media, such as agarose and cellulose.

In addition, it would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically utilizing Protein A as the affinity tag because the modified Hargro discloses utilizing a media which is known in the art to contain materials that bind to an affinity tag of choice. Thus, it would be

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desirable to have Protein A as the affinity tag of choice to isolate particular protein complexes bound to the tagged protein of interest.

11. **Claims 8 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro in view of Tuvim, as applied to claims 1-6, 9-12, 14-15, and 18-22 above, and further in view of Hunt et al. ("Hunt," US Pub. No. 2002/0110495).

The disclosure of Hargro is discussed above. Modified Hargro does not specifically disclose having a bed volume of less than 20 microliters and an extraction media chamber at most 1000 microliters.

Hunt discloses a device for the purification and separation of substances. The purification device comprises a sample holder comprising a sample chamber and a column module. The column module is securable to the sample holder and is packed with chromatography medium having a special affinity for attracting a given substance. (abstract). Hunt further discloses a microcolumn with a single bed volume, 0.02 to 0.1 ml, in paragraph [0020].

It would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically having a bed volume of less than 20 microliters and an extraction media chamber at most 1000 microliters because it would be advantageous to utilize microscale-sized components for a microscale chromatography column.

12. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro in view of Tuvim, as applied to claims 1-6, 9-12, 14-15, and 18-22 above, and further in view of Halmann et al. ("Halmann," US 4302534).

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The disclosure of Hargro is discussed above. Modified Hargro does not specifically disclose having a bed of extraction media having a dry weight of less than 10 mg.

Halmann discloses a heterogenous enzymatic immunoassay, in which chemiluminescence is employed as a detection means. Halmann discloses in example 2, a standard assay procedure comprising about 1mg dry weight of anti-SEB-Sepharose, solution to be tested, and saline solution (i.e. column 7, lines 1-40).

It would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically utilizing less than 10mg dry weight of Sepharose because it would be beneficial to utilize a limited amount of chromatography media for microscale sized chromatography columns to insure a reasonable amount of chromatography media is packed inside the column.

Response to Arguments

13. Applicant's arguments, see p. 1-13, filed 2/15/08, with respect to the rejection(s) of claim(s) 1-22 under Colpan; Brewer in view of Colpan; Hargro in view of Colpan; Hargro in view of Colpan, and further in view of Smith; Hargro in view of Colpan, and further in view of Hunt; and Hargro in view of Colpan, and further in view of Halmann have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tuvim, Brewer in view of Tuvim; Hargro in view of Tuvim; Hargro in view of Tuvim, and further in

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view of Smith; Hargro in view of Tuvim, and further in view of Hunt; and Hargro in view of Tuvim, and further in view of Halmann.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
Art Unit 1797